November 18, 2004

Via fax and UPS

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0440
Draft Guidance for Industry on Computerized Systems Used in Clinical Trials [Federal Register Volume 69, No. 191, pages 59239-59240, October 4, 2004]

Dear Sir/Madam:

Aventis Pharmaceuticals appreciates the opportunity to comment on the above-referenced Draft Guidance entitled "*Computerized Systems Used in Clinical Trials*".

This draft guidance provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA.

We generally agree with the content in the guidance and offer the following comments for your consideration.

GENERAL COMMENTS:

We suggest that this guidance be carefully examined against the current effective 21CFR Part11 guidance(s) in order to ensure alignment.

SPECIFIC COMMENTS:

II. BACKGROUND
Line 60-61: *Computerized medical devices, diagnostic laboratory instruments in analytical laboratories that are used in clinical trials are not the subject of this guidance.*

These devices whether in a hospital setting affiliated with the study site or in an analytical laboratory serving the study site, generate the source-data. During the study the study monitors and quality personnel verify the source-data in order to determine it's reliability. Exclusion of these systems may diminish Sponsor's regulatory justification to compel above organizations to have the correct technical and procedural controls to safeguard the accuracy, completeness and reliability of the source-data.

Aventis Pharmaceuticals Inc. • 200 Crossing Boulevard • PO Box 6890 • Bridgewater, NJ 08807-0890 • www.aventis.com
Telephone (908) 304-7000

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III. GENERAL PRINCIPLES

Line 80: *We also recommend that this documentation be retained as part of the study records.*

The wording seems prescriptive. We suggest the following: "*We recommend that this documentation be retained for the same period of time as the study records and available for Agency review and copying.*"

V. STANDARD OPERATING PROCEDURES

Lines 143: *Data Backup, Recovery, and Contingency Plans*
Line 146: *Alternative Recording Methods (in the case of system unavailability)*

The concept in Lines 143 and 146 referencing 'contingency plans and alternate recording methods' are similar. If the two items are materially different, we request an explanation of the differences.

VIII. System SECURITY

Lines 291-292: *SOPs should be developed and implemented for handling and storing the system to prevent unauthorized access.*

We request clarification on what is meant by "*handling and storing the system ...*" We assume the wording is meant to read as handling and storing the *data within the system.*

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on the *Draft Guidance for Industry on Computerized Systems Used in Clinical Trials* and are much obliged for your consideration.

Sincerely,

Steve Caffé, M.D.
Vice President, Head US Regulatory Affairs